

Economic Impact Statement

LSA Document #16-530

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

The Indiana Family and Social Services Administration (FSSA) Office of Medicaid Policy and Planning (OMPP) proposes to amend [405 IAC 5-24](#) to modify the reimbursement methodology for legend drugs, modify the calculation of the professional dispensing fee, and update and clarify definitions and terminology. These changes are necessary in order to comply with federal regulations set forth in the Covered Outpatient Drugs final rule issued by the Centers for Medicare and Medicaid Services (CMS) on January 21, 2016. This final rule establishes actual acquisition cost (AAC) as the basis for Medicaid ingredient cost reimbursement, implements the terminology "professional dispensing fee" to ensure that the dispensing fee paid to pharmacies reflects the cost of the pharmacist's professional services and cost to dispense the drug to a Medicaid beneficiary, and clarifies that states are required to evaluate the sufficiency of both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing changes to either of these components.

Impact on Small Business

The following section provides responses to the following questions outlined in [IC 4-22-2.1-5](#):

1. An estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.

[IC 5-28-2-6](#) defines a small business as a business entity that satisfies the following requirements:

- (1) On at least fifty percent (50%) of the working days of the business entity occurring during the preceding calendar year, the business entity employed not more than one hundred fifty (150) employees.
- (2) The majority of the employees of the business entity work in Indiana.

The OMPP estimates that out of a total of 1,208 Medicaid-enrolled providers in Indiana that are impacted by these changes, there are 193 providers that may meet the criteria of a small business.

2. An estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

The proposed rule amendment will not impose any additional annual reporting, record keeping, or other administrative costs on small businesses in order to comply with the proposed rule. This rule amendment modifies the reimbursement methodology for legend drugs, modifies the calculation of the professional dispensing fee, and updates and clarifies definitions and terminology, but it does not place new requirements on small businesses.

3. An estimate of the total annual economic impact that compliance will have on small businesses subject to the rule.

There is no economic impact that compliance will have on a small business subject to this rule because small businesses will not incur any additional cost to comply with this rule.

4. A statement justifying any requirement or cost that is imposed by the rule and not expressly required by law. The statement must reference any data, studies, or analyses relied upon by the agency in determining imposition of the requirement or cost is necessary.

The proposed rule amendment modifies reimbursement methodologies as required by federal law, and may result in a change in Medicaid reimbursement to small businesses. However, the rule will not impose any requirement or cost on small businesses in order to comply with the proposed rule.

5. Any regulatory flexibility analysis that considers any less intrusive or less costly alternative methods of achieving the same purpose.

Other factors considered:

A. Establishment of less stringent compliance or reporting requirements for small businesses.

The rule does not add any new reporting requirements for small businesses. Less stringent compliance or reporting requirements would not ensure that Medicaid reimbursement methodologies are changed to comply with new federal regulations.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

The rule has no impact on schedules or deadlines for compliance or reporting requirements for small businesses. Less stringent schedules or deadlines would not implement the changes in the proposed rule.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

The rule has no impact on compliance or reporting requirements for small businesses. Consolidation or simplification of compliance reporting requirements would not implement the changes in the proposed rule.

D. Establishment of performance standards for small businesses instead of design or operational

standards imposed on other regulated entities by the rule.

The rule has no impact on performance or operational standards for small businesses. Establishing performance standards for small businesses would not ensure that Medicaid reimbursement methodologies are changed to comply with new federal regulations.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.

The rule imposes no additional requirements or cost on small businesses, so exempting small businesses from the proposed rule would not achieve the rule's purpose of modifying Medicaid reimbursement methodologies to comply with new federal regulations.

If there are any programmatic or fiscal questions, please contact Marc Shirley at (317) 232-4343 or at marc.shirley@fssa.in.gov. Questions regarding any other aspect of the proposed changes should also be addressed to Leslie Huckleberry at (317) 232-1246 or at leslie.huckleberry@fssa.in.gov.

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